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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,442	12/12/2003	Qiong Cheng	CL2027 US NA	2513

23906 7590 10/16/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/735,442

Applicant(s)

CHENG ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 9-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. Claims 1-5, and 9-27 are pending in the instant application. Claims 17-27 have been previously withdrawn from consideration as drawn to a non-elected invention.
2. Claims 1-5 and 9-16 are under consideration in this Office Action.
3. The rejection of claims 1-5 under 35 USC 101 as being directed to non-statutory subject matter has been withdrawn in view of applicants' amendment to the claims filed 07/13/2006.
4. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment to the claims filed 07/13/2006.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The arguments filed 07/13/2006 have been fully considered but are not persuasive for reasons of record as supplemented below.

As stated in the previous Office Action, the claims are genus claims which are drawn to a genus of carotenoid overproducing bacteria comprising a genus of genes encoding a functional carotenoid enzymatic biosynthetic pathway wherein any *dxs*, *idi*, and *ygbBP* genes of any nucleotide sequence and structure are overexpressed and wherein any *yjeR* gene of any nucleotide sequence and structure is down regulated. The scope of the genus of carotenoid overproducing bacteria includes many members with widely differing biochemical and biophysical properties. The scope of the genus of genes encoding a functional carotenoid enzymatic biosynthetic pathway includes many members with widely differing

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structural, chemical, and physiochemical properties including widely differing nucleotide or amino acid sequences. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exist.

The specification discloses two *E. coli* carotenoid overproducing strains identified as ATCC PTA-4807 and ATCC PTA-4823. The specification discloses the following genes from *Pantoea stewartii* and their respective nucleotide SEQ ID NO identifiers: CrtE (SEQ ID NO: 1), CrtX (SEQ ID NO: 3), CrtY (SEQ ID NO: 5), CrtI (SEQ ID NO: 7), CrtB (SEQ ID NO: 9), and CrtZ (SEQ ID NO: 11) [see p. 5]. The specification discloses the following genes from *Methylobacter* 16a and their respective nucleotide SEQ ID NO identifiers: dxs (SEQ ID NO: 13), lytB (SEQ ID NO: 15), and dxr (SEQ ID NO: 17) [see p. 6]. The specification discloses that SEQ ID NO: 63 is the nucleotide sequence of a mutant yjeR gene, which is identified as yjeR::Tn5.

However, the specification does not describe and define any properties, such as structural features and nucleotide or amino acid sequences, which are commonly possessed by members of each claimed genus. For example, the specification does not describe and define any structural features and nucleotide or amino acid sequences commonly possessed by yjeR genes from biological sources other than the disclosed mutant yjeR gene of SEQ ID NO: 63. Furthermore, the specification does not describe and define any properties commonly shared between members of the claimed genus of carotenoid overproducing bacteria. The specification does not provide additional species within this genus, other than ATCC PTA-4807 and ATCC PTA-4823, which are representative of the claimed genus of carotenoid overproducing bacteria. Thus, one skilled in the art cannot predict and visualize or recognize the identity of the members of each genus for use in the claimed method.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of carotenoid overproducing bacteria comprising a genus of genes encoding a functional carotenoid enzymatic biosynthetic pathway wherein any dxs, idi, and ygbBP genes of any nucleotide sequence and structure are overexpressed and wherein any yjeR gene of any nucleotide sequence and structure is down regulated. Dependent claims 9-15 are also rejected because they do not correct the defect of claims 1 or 2.

Furthermore, as stated in the previous Office Action claims encompass the genes dxs, dxr, yggP, ychB, ygbB, lytB, idi, ispA, ispB, crtE, crtB, crtI, crtY, crtZ, crtW, and yjeR. Gene elements which are not particularly described, including promoter regions, regulatory elements, and untranslated regions, are essential to the function of the claimed invention since the claims recite "gene". The art indicates that the structure of these gene elements are empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of a polynucleotide

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encoding a protein or enzyme and the structure of the non-described promoter regions, regulatory elements, and untranslated regions. In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of any *dxs*, *dxr*, *ygpP*, *ychB*, *ygbB*, *lytB*, *idi*, *ispA*, *ispB*, *crtE*, *crtB*, *crtI*, *crtY*, *crtZ*, *crtW*, and *yjeR* gene.

Amending the claims to recite polynucleotides encoding the following polypeptides and corresponding SEQ ID NO identifiers which enables the transformed *E.coli* to overproduce carotenoids compared to an untransformed *E.coli* may overcome the rejection: *CrtE* (SEQ ID NO: 1), *CrtX* (SEQ ID NO: 3), *CrtY* (SEQ ID NO: 5), *CrtI* (SEQ ID NO: 7), *CrtB* (SEQ ID NO: 9), *CrtZ* (SEQ ID NO: 11), *dxs* (SEQ ID NO: 13), *lytB* (SEQ ID NO: 15), *dxr* (SEQ ID NO: 17), and SEQ ID NO: 63.

7. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated *E.coli* host cell transformed with a polynucleotide comprising SEQ ID NO: 63 which encodes a mutant oligoribonuclease, where said isolated *E.coli* cell comprises a functional carotenoid enzymatic biosynthetic pathway consisting of the proteins of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, and 18; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The arguments filed 07/13/2006 have been fully considered but are not persuasive for reasons of record as supplemented below. As stated in the previous Office Action, the specification provides guidance and working examples for two *E.coli* carotenoid-overproducing strains identified as ATCC PTA-4807 and ATCC PTA-4823. The specification guidance and working examples for the following genes from *Pantoea stewartii* and their respective nucleotide SEQ ID NO identifiers: *CrtE* (SEQ ID NO: 1), *CrtX* (SEQ ID NO: 3), *CrtY* (SEQ ID NO: 5), *CrtI* (SEQ ID NO: 7), *CrtB* (SEQ ID NO: 9), and *CrtZ* (SEQ ID NO: 11) [see p. 5]. The specification provides guidance and working examples for the following genes from *Methylobacter* 16a and their respective nucleotide SEQ ID NO identifiers: *dxs* (SEQ ID NO: 13), *lytB* (SEQ ID NO: 15), and *dxr* (SEQ ID NO: 17) [see p. 6]. The specification provides guidance and working examples for SEQ ID NO: 63, which is the nucleotide sequence of a mutant *yjeR* gene that is identified as *yjeR::Tn5*.

However, the specification does not provide guidance, prediction, and working examples for any other carotenoid overproducing bacteria comprising any genes encoding a functional carotenoid enzymatic biosynthetic pathway wherein any *dxs*, *idi*, and *ygbBP* genes of any nucleotide sequence and structure are overexpressed and wherein any *yjeR* gene of any

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nucleotide sequence and structure is down regulated. The specification does not provide guidance, prediction, and working examples for any of the genes *dxs*, *dxr*, *ygpP*, *ychB*, *ygbB*, *lytB*, *idi*, *ispA*, *ispB*, *crtE*, *crtB*, *crtI*, *crtY*, *crtZ*, *crtW*, and *yjeR* from any biological source and nucleotide sequence and structure.

The examiner maintains that undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any carotenoid overproducing bacteria comprising any genes encoding a functional carotenoid enzymatic biosynthetic pathway, wherein any *dxs*, *idi*, and *ygbBP* genes of any nucleotide sequence and structure are overexpressed and wherein any *yjeR* gene of any nucleotide sequence and structure is down regulated; and then determining whether the bacteria can overproduce any carotenoid. General teachings from the specification regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

Amending the claims to recite polynucleotides encoding the following polypeptides and corresponding SEQ ID NO identifiers which enables the transformed *E.coli* to overproduce carotenoids compared to an untransformed *E.coli* may overcome the rejection: *CrtE* (SEQ ID NO: 1), *CrtX* (SEQ ID NO: 3), *CrtY* (SEQ ID NO: 5), *CrtI* (SEQ ID NO: 7), *CrtB* (SEQ ID NO: 9), *CrtZ* (SEQ ID NO: 11), *dxs* (SEQ ID NO: 13), *lytB* (SEQ ID NO: 15), *dxr* (SEQ ID NO: 17), and SEQ ID NO: 63.

### ***Conclusion***

8. Claim 16 is allowed.

9. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
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